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## **Juvèderm™**

### **What is it?**

**Juvèderm™ Ultra and Ultra Plus** injectable gel is a colorless hyaluronic acid gel that is injected into facial tissue to smooth wrinkles and folds, especially around the nose and mouth. Hyaluronic acid is a naturally occurring sugar found in the human body. The role of hyaluronic acid in the skin is to deliver nutrients, hydrate the skin by holding in water, and to act as a cushioning agent.

### **What does it do?**

**Juvèderm™ Ultra and Ultra Plus** injectable gel temporarily adds volume to facial tissue and restores a smoother appearance to the face.

### **How is it used?**

**Juvèderm™ Ultra and Ultra Plus** injectable gel temporarily adds volume to facial tissue and restores a smoother appearance to the face.

### **What will it accomplish?**

**Juvèderm™ Ultra and Ultra Plus** injectable gel will help to smooth moderate to severe facial wrinkles and folds. Most patients need one treatment to achieve optimal wrinkle smoothing, and the results last about one year.

### **What are the possible side effects?**

Most side effects are mild or moderate in nature, and their duration is short lasting (7 days or less). The most common side effects include, but are not limited to: temporary injection-site reactions such as redness, pain/tenderness, firmness, swelling, lumps/bumps, bruising, itching, and discoloration. As with all skin injection procedures, there is a risk of infection.

### **Are there any reason why I should not receive Juvèderm™ Ultra and Ultra Plus injectable gel?**

Your physician will ask about your history to determine if you are an appropriate candidate for treatment. **Juvèderm™ Ultra and Ultra Plus** injectable gel should not be used in patients who have:

- Severe allergies marked by history of anaphylaxis or history or presence of multiple severe allergies
- Patients with a history of allergies to Gram-positive bacterial proteins



### **What should my physician advise me about?**

The following are important treatment considerations for you to discuss with our physician and understand in order to help avoid unsatisfactory results and complications.

- Patients who are using substances that can prolong bleeding, such as aspirin or ibuprofen, as with any injections, may experience increased bruising or bleeding at injection site. You should inform your physician before treatment if you are using these types of substances.
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with **Juvèderm™ Ultra and Ultra Plus** injectable gel there may be an increased risk of infection.
- **Juvèderm™ Ultra and Ultra Plus** injectable gel should be used with caution in patients on immunosuppressive therapy or therapy used to decrease the body's immune response, as there may be an increased risk of infection.
- The safety of **Juvèderm™ Ultra and Ultra Plus** injectable gel for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established.
- The safety of **Juvèderm™ Ultra and Ultra Plus** injectable gel in patients with a history of excessive scarring (e.g. Hypertrophic scarring and keloid formations) and pigmentation disorders has not been studied.

### **What should my physician warn me about?**

The safety and effectiveness of **Juvèderm™ Ultra and Ultra Plus** injectable gel for the treatment of areas other than facial wrinkles and folds (such as lips) have not been established in controlled clinical studies.

### **What did the clinical study show?**

In a US clinical study, 146 subjects were followed for 24 weeks after injection with **Juvèderm™ Ultra** injectable gel in one nasolabial fold and **ZYPLAST®** dermal filler (bovine-based collagen) in the other. Injection-site responses were similar in duration and frequency for **Juvèderm™ Ultra** injectable gel and **ZYPLAST®** dermal filler treated sides, were usually mild or moderate in severity, did not require intervention, and lasted 7 days or less.

**Juvèderm™ Ultra** injectable gel was found to provide a more persistent wrinkle correction than **ZYPLAST®** dermal filler over 24-week course of the study. The percentage of subjects who maintained improvement with **Juvèderm™ Ultra** injectable 24 was 88% compared to 36% with **ZYPLAST®** dermal filler. At the conclusion of the study, 129 (88%) of the 146 subjects expressed a preference for **Juvèderm™ Ultra** injectable gel, while only 8 (5%) expressed a preference for **ZYPLAST®** dermal filler, and 9 (6%) had no preference.



### **Do the injections hurt?**

Injections may cause some discomfort during and after the injection. **Juvèderm™ Ultra and Ultra Plus** injectable gel is injected directly into the skin using a fine needle to further minimize discomfort. Physicians may choose to numb (anesthetize) the treatment area to further minimize discomfort.

### **What should I expect following the procedure?**

You physician will tell you what to expect following treatment **Juvèderm™ Ultra and Ultra Plus** injectable gel. Within the first 24 hours, you should avoid strenuous exercise, extensive sun or heat exposure, and alcoholic beverages. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites. If there is swelling, you may need to place an ice pack over the swollen area. You should ask your physician when makeup may be applied after your treatment.

### **Does the correction last forever?**

No. Correction is temporary; therefore, touch-up injections as well as repeat injections are usually needed to maintain optimal correction.

### **What other treatments are available to me?**

Other treatments for dermal soft tissue augmentation include bovine-based collagen and other hyaluronic acid-based dermal fillers. Aside from these treatments, additional options for the correction of lines and wrinkles do exist, including facial creams, BOTOX® Cosmetic (Botulinum Toxin Type A), chemical peels, and laser skin surface treatments, all of which may be discussed with your physician.

### **When should I notify my physician?**

Be sure to report any redness and/or visible swelling that lasts for more than a few days or any other symptoms that cause you concern to your physician and/or contact the **Allergan Product Support line at 1-877-345-5372.**

**For further questions and information please call the office at 210-614-0400.**